

HACH ROSE SCHIRIPA & CHEVERIE LLP

ATTORNEYS AT LAW

October 8, 2015

VIA ECF

The Honorable Katharine S. Hayden
United States District Judge
District of New Jersey
Martin Luther King Building & U.S. Courthouse
50 Walnut Street, Court Room: PO 05
Newark, NJ 07101

Re: *In re Thalomid and Revlimid Antitrust Litigation*,
Civil Action No. 14-6997 (KSH) (CLW)

Dear Judge Hayden:

On behalf of Plaintiffs International Union of Bricklayers and Allied Craft Workers Local 1 Health Fund and City of Providence ("Plaintiffs"), we submit this response to Defendant Celgene Corporation's ("Celgene" or "Defendant") letter regarding a Memorandum Opinion and Order in *Natco Pharma Ltd v. Gilead Sciences, Inc., et al*, No. 14-3247 (D. Minn. Sept. 29, 2015) ("*Gilead Sciences*"). The facts underlying the decision in *Gilead Sciences* are readily distinguishable. Namely, in contrast to the efforts of the generic drug manufacturers attempting to obtain Thalomid and Revlimid described in Plaintiffs' complaint, in *Gilead Sciences*, Natco did not attempt to meet REMS requirements on Letairis before filing its complaint. *See Gilead Sciences* at 4-6.

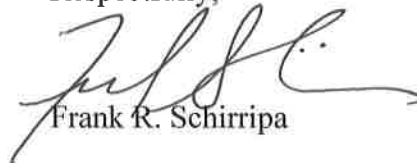
Here, Plaintiffs' complaints detail the steps that Mylan and other generic competitors undertook to comply with Celgene's demands. (*See* Dkt. 1, ¶¶ 70-122; City of Providence Complaint, ¶¶ 61-105.) Indeed, this includes Lannett and Mylan pursuing and obtaining letters from the FDA itself stating that Celgene could provide the necessary samples to Mylan *without violating* the REMS protocol, thus eliminating any legitimate business concerns. (Dkt. 1, ¶¶ 90-91, 104-107; City of Providence Complaint, ¶¶ 74-75, 88-91.) Also unlike *Gilead Sciences* with Letairis, Celgene has provided samples of Thalomid and Revlimid to entities that were not potential competitors (*e.g.*, Dkt. 1, ¶¶ 76-77; City of Providence Complaint, ¶¶ 65-66), demonstrating that its reliance on the REMS protocol is anticompetitive pretext only wielded when refusing to deal with potential competitors.

Tellingly, when the same core set of facts here at issue were put before the Honorable Judge Esther Salas in Mylan's case against Celgene over Celgene's refusal to sell Thalomid and Revlimid samples, the court found that Mylan had sufficiently pled a refusal to deal and therefore denied Celgene's motion to dismiss. *Mylan Pharms., Inc. v. Celgene Corp.*, No. 14-cv-2094 (D. N.J. Dec. 22, 2014) (Salas, J), *interlocutory appeal denied*, No. 15-8017 (3d Cir. Mar. 5, 2015). (*See also*, Dkt. 29 at 7-9, 18-22.) It is also notable that the *Gilead Sciences* court similarly left the door open for antitrust claims based on a theory of anticompetitive abuse of the REMS process to preclude generic competition, where (as here) such a claim is supported by the facts. *Gilead Sciences* at 19-20.

Hon. Katharine S. Hayden
October 8, 2015
Page 2

In sum, Plaintiffs in the instant case have clearly pled that Celgene continued to refuse to deal with potential generic competitors long after those potential competitors had complied with Celgene's numerous demands and quelled any legitimate business concern Celgene had for refusing to provide the requested samples of Thalomid and/or Revlimid. Plaintiffs therefore respectfully submit that Defendant's Motion to Dismiss should be denied for the reasons stated herein and in the briefing submitted to the Court.

Respectfully,



Frank R. Schirripa

Enclosure

cc: All Counsel of Record (*via* ECF)